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EXAMINER	
GAMBEL, PHILLIP	

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,384	LAWSON ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/13/2009, 11/02/2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-25* is/are pending in the application.

4a) Of the above claim(s) *13-14, 20 and 23-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12, 15-19 and 21-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/02/2009 has been entered.

Applicant's amendment, filed 10/13/2009, has been entered.

Claims 15-17 have been amended.

Claims 1-11 have been canceled previously.

Claims 12-25 are pending.

Claims 12, 15-19 and 21-22 are under consideration as they read on treating inflammatory bowel disease (e.g., ulcerative colitis and Crohn's disease) with anti-CSF-1 antibody (i.e., anti-M-CSF antibody) as they read on the elected invention and species.

Claims 13-14, 20 and 23-25 have been withdrawn from further consideration by the examiner as being drawn to a nonelected inventions and/or species.

2. This Office Action will be in response to applicant's amendment, filed 10/13/2009.

The rejections of record can be found in the previous Office Action, mailed 12/10/2008.

3. Upon reconsideration of applicant's amended claims, filed 10/13/2009; the previous rejection under 35 U.S.C. § 112, second paragraph, has been withdrawn.

4. Petition to Correct Inventorship.

The petition to correct the inventorship and supporting papers, filed 10/13/2009, of this application under 37 C.F.R. § 1.48(a) requesting addition of an inventor are deficient because of the following issue.

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the city and either state or foreign country of residence of each inventor (e.g., Diane Marshall). The residence information may be provided on either an application data sheet or supplemental oath or declaration.

It does not identify the citizenship of each inventor (e.g., Diane Marshall).

It does not identify the mailing address of each inventor (e.g., Diane Marshall). A mailing address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing address should include the ZIP Code designation. The mailing address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

5. Declaration of Lawson, Marshall and Bourne under 37 C.F.R. § 1.131.

The 1.131 declaration is deficient for several reasons.

A) Given the defective oath/declaration in conjunction with applicant's petition to add an inventor,
Diane Marshall has not been added as inventor at this time.

B) *If Diane Marshall was to be added as an inventor*,
it is noted that applicant's Declaration under 37 CFR 1.131 by Lawson, Marshall and Bourne, while sufficient to overcome the rejection of record as it applies to claims 15-17 and 19, as currently recited, is deemed to be ineffective to overcome the rejection as it applies to claims 12 and 21-22, for the following reason.

Applicant's Declaration under 1.131 would not sufficient in scope of disclosure, relative to the scope of the instant claims and the scope of teachings in the prior art.
For example, the Declaration and supporting evidence is limited to CSF-1-specific antibodies as the inhibitor of CSF-1 activity, while claims 12 and 21-22 encompass a broader scope of inhibitors of CSF-1 activity.

For the record, it is noted
that while the Declaration and supporting evidence is limited to monoclonal CSF-1-specific antibodies, the claimed antibody equivalents (e.g., see claims 15-17 and 19) would have been obvious equivalents at the time the invention was made;
that while the Declaration and supporting evidence is limited to an experimental model of colitis, this model provided sufficient conception, diligence and constructive reduction to practice of treating inflammatory bowel disease, as recited in the instant claims; and
that the ordinary artisan accepted the well known meaning of IBD as referring to serious, chronic disorders of the intestinal tract characterized by chronic inflammation at various sites in the gastrointestinal tract, and specifically includes ulcerative colitis OAC) and Crohn's disease (CD) (e.g., see. As page 1, paragraph 3 of the instant specification

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 12, 15-19 and 21-22 stand rejected under 35 U.S.C. § 102(e) as being anticipated by over Bedian et al. (US 2005/0059113) (see entire document)

and as further evidence that CSF-1 is also known as M-CSF at the time the invention was made, as acknowledged on page 1, paragraph 2 of the instant specification essentially for the reasons of record.

Applicant's arguments, in conjunction with the Declaration, filed under 37 CFR 1.131, filed 10/13/2009 , have been fully considered but have not been found convincing, given the reasons set forth above in Section 5.

The following of record is reiterated for applicant's convenience.

Applicant's arguments, in conjunction with Impax Laboratories, Inc. v. Aventis Pharmaceuticals Inc., 88 USPQ2d 1381 (Fed. Cir. 2008), filed 04/21/2009, have been fully considered but have not been found convincing essentially for the reasons of record.

When the species is clearly named, the species claim is anticipated no matter how many other species are additionally named

See Ex parte A, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990).

Also, see MPEP 2131.02.

A reference contains an enabling disclosure if the public was in possession of the claimed invention before the dat4e of invention. Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his or her own knowledge to make the claimed invention .

See In re Donohue, 226 USPQ 619 (Fed. Cir. 1985).

Also, see MPEP 2121.01.

The proper issue is whether the prior art is enabling in the sense that is describes the claimed invention sufficiently to enable a person of ordinary skill in the art to carry out the invention.

For example, see Impax Laboratories, Inc. v. Aventis Pharmaceuticals Inc., 81 USPQ2d 1001 (Fed. Cir. 2006).

With respect to applicant's reliance on Impax Laboratories, Inc. v. Aventis Pharmaceuticals Inc., 88 USPQ2d 1381 (Fed. Cir. 2008),

Bedian et al. is directed to anti-M-CSF antibodies and not to a particularly large number of compounds (as found in Impax)

along with clear teachings of making and using antagonistic anti-M-CSF antibodies (e.g., see paragraphs [0098] – [0102], [0180], 0222] –[0223], [0236]-[0237]),

along with clear teachings of providing effective amounts and dosage regimens that can be adjusted to the individual need and the professional judgment of the person administering or supervising the administration (e.g., see paragraph [0260] - [0262]),

along with the clear teaching of treating Crohn's disease and ulcerative colitis (e.g., see paragraph [0249]);

as well as Examples of making and using antagonistic anti-M-CSF antibodies in in vitro and in vivo assays (e.g., see Examples I- X on pages 29-33).

The prior art teaching is consistent with applicant's own disclosure that inhibitors of CSF-1 activity were well known in the art as were the methods of identifying and producing such inhibitors (e.g., see page 4, paragraph 2 of the instant specification), techniques were known to physicians familiar with IBD that could be used to determine whether a candidate agent has altered one or more symptoms associated with the disease (e.g., see page 14, paragraph 3 of the instant specification) and that the dosage to be administered of CSF-1 activity will vary according to the particular inhibitor, the type of IBD, the subject and the nature of severity of the disease and the physical condition of the subject ,which can be readily determined by the person skilled in the art (e.g., see page 18, paragraph 6 of the instant specification).

The issue of enablement under 35 USC 102 is a question of whether one of ordinary skill in the art would know how to make and use the invention based on the reference's disclosure and that the standard for enablement of a prior art reference for purposes of anticipation under 102 differs from the enablement standard under 35 USC 112.

See In re Gleave, 90 USQP2d 1235, 1238 (Fed. Cir. 2009).

In contrast to applicant's arguments, the prior art clearly teaches the claimed methods in a manner for the ordinary person to practice or carry out the claimed methods of treating IBD with anti-M-CSF antibodies.

The arguments of counsel cannot take the place of evidence in the record. In re Schulze , 145 USPQ 716, 718 (CCPA 1965).

The following is reiterated for applicant's convenience.

Bedian et al. teach methods of treating various conditions encompassing inflammatory bowel disease, Crohn's disease and ulcerative colitis (e.g., see paragraph [0249]), with anti-M-CSF antibodies, including antibody fragments (e.g., see paragraphs [0098] – [0102], [0180], 0222] –[0223], [0236]-[0237]), therapeutic conjugates thereof (e.g., see paragraphs [0127] – [0128], [0241] – [0246]) and biocompatible polymers thereof (e.g., derivatives; e.g., see paragraph [0255]) (see paragraphs [0098] - [0246], [0247] –[0263]).

Applicant's arguments have not been found persuasive

9. Claims 12, 15-17, 19 and 21-22 are rejected under 35 U.S.C. § 102(e) as being anticipated by Devalaraja et al. (U.S. Patent No. 7,108,852) and as further evidenced by page 1, paragraph 3 of the instant specification with respect to the well known meaning of IBD by the ordinary artisan at the time the invention was made.

Devalaraja et al. teach treating various inflammatory conditions, including inflammatory bowel disease (e.g., see column 7, paragraph 1) with inhibitors of CSF, including antibody directed to CSF (e.g., column 4, paragraphs 1-5) and Detailed Description of the Invention (e.g., see column 10, paragraph 1; column 11, paragraph 6-9; column 13, paragraph 6 - column 14, paragraph 1) and Claims.

Devalaraja et al. notes that M-CSF was also known as colony stimulating factor-1 in the Background of the Invention (also, see in particular column 1, paragraph 3 of the Background) and the Summary of the Invention (see column 4 in particular).

As page 1, paragraph 3 of the instant specification acknowledges,
The ordinary artisan accepted the well known meaning of IBD as follows.
The term "inflammatory bowel disease" (IBD) refers to serious, chronic disorders of the intestinal tract characterised by chronic inflammation at various sites in the gastrointestinal tract, and specifically includes ulcerative colitis OAC) and Crohn's disease (CD).

10. Claims 12, 15-17, 19 and 21-22 are rejected under 35 U.S.C. § 102(e) as being anticipated by Hamilton et al. (U.S. Patent No. 7,455,836) and as further evidenced by page 1, paragraph 3 of the instant specification with respect to the well known meaning of IBD by the ordinary artisan at the time the invention was made.

Hamilton et al. teach methods of treating inflammatory conditions, such as inflammatory bowel disease and Crohn's disease (e.g., see Background of the Invention; column 5, paragraph 6; Claim 13)with antagonists of colony stimulating factor-receptor interactions, including colony stimulating factors such as M-CSF (e.g., see Summary of the Invention, Detailed Description of the Preferred Embodiments), including antibodies (e.g., see column 8, paragraphs 2 and 9; column 10, paragraph 2; column 12, paragraph 4; and Example 2).

11. Claims 12, 15-19 and 21-22 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Devalaraja et al. (U.S. Patent No. 7,108,852) AND/OR Hamilton et al. (US 7,455,836) in view of Buschmann et al. (U.S. Patent No. 7,507,705), Renner et al. (US 2004/0053365) and as further evidenced by page 1, paragraph 3 of the instant specification with respect to the well known meaning of IBD by the ordinary artisan at the time the invention was made.

Devalaraja et al. teach treating various inflammatory conditions, including inflammatory bowel disease (e.g., see column 7, paragraph 1) with inhibitors of CSF, including antibody directed to CSF (e.g., column 4, paragraphs 1-5) and Detailed Description of the Invention (e.g., see column 10, paragraph 1; column 11, paragraph 6-9; column 13, paragraph 6 - column 14, paragraph 1) and Claims.

Devalaraja et al. notes that M-CSF was also known as colony stimulating factor-1 in the Background of the Invention (also, see in particular column 1, paragraph 3 of the Background) and the Summary of the Invention (see column 4 in particular).

Hamilton et al. teach methods of treating inflammatory conditions, such as inflammatory bowel disease and Crohn's disease (e.g., see paragraphs [0004], [0036])with antagonists of colony stimulating factor-receptor interactions, including colony stimulating factors such as M-CSF (e.g., see Summary of the Invention, Detailed Description of the Preferred Embodiments) including antibodies (e.g., see paragraphs [0040], [0062], [0073]).

Devalaraja et al. and Hamilton et al. differ from the claimed methods by not describing all of the well known functional equivalents of recombinant antibodies and antigen-binding fragments thereof at the time the invention was made.

Renner et al. teach methods of treating inflammatory conditions, with antagonists encompassing the well known functional equivalents of recombinant antibodies and antigen-binding fragments thereof, including chimeric and humanized antibodies as well as Fab and $F(ab')_2$ (e.g., see pages 1-3). at the time the invention was made, including the use of such antibodies in the context of the colony stimulating factor GM-CSF and inflammatory bowel disease (e.g., see paragraph [0040]) (see entire document, including Background and Prior Art, Summary of the Invention and Detailed Description of the Invention).

Similarly, Buschmann et teach the well known functional equivalents of recombinant antibodies and antigen-binding fragments thereof, including monoclonal, polyclonal and synthetic antibodies as well as Fab, Fv and scFv fragments (e.g., see column, 9,paragraph 6; column 10, paragraph 3 -column 11, paragraph 1), at the time the invention was made, including the use of such antibodies in the context of the colony stimulating factors, including M-CSF (e.g., see column 5, paragraph 31) (see entire document).

Consistent with the prior art teachings and as page 1, paragraph 3 of the instant specification acknowledges,
the ordinary artisan accepted the well known meaning of IBD as follows.

The term "inflammatory bowel disease" (IBD) refers to serious, chronic disorders of the intestinal tract characterized by chronic inflammation at various sites in the gastrointestinal tract, and specifically includes ulcerative colitis OAC) and Crohn's disease (CD).

One of ordinary skill in the art at the time the invention was made would have been motivated to select various equivalent forms of CSF-1-/M-CSF-1-specific antibodiess having antagonistic properties in order to inhibit undesirable responses in inflammatory bowel disease at the time the invention was made;
given the teachings of Devalaraja et al. and Hamilton et al. to treat inflammatory bowel disease with antagonistic antibodies specific for CSF-1-/M-CSF-1 and the well known use of various antibody equivalents, including conjugated antibodies to one or more effector molecules, taught by Devalaraja et al. and Hamilton et al., as well as Renner et al. and Buschmann et al. in the context of therapeutic methods targeting colony stimulating factors as well as well known practiced by the ordinary artisan at the time the invention was made.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

"The test of obviousness is not express suggestion of the claimed invention in any or all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them." See In re Rosselet, 146 USPQ 183, 186 (CCPA 1965).

"There is no requirement (under 35 USC 103(a)) that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art." Motorola, Inc. v. Interdiqital Tech. Corp., 43 USPQ2d 1481, 1489 (Fed. Cir. 1997).

An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. See KSR Int'l Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.").

Given that the prior art goal was to treat inflammatory disease with CSF-1-specific antibodies, incorporating known methods of treating inflammatory conditions, including inflammatory bowel disease, with functional equivalents of antagonistic therapeutic antibodies including conjugated antibodies to one or more effector molecules would have been routine to the ordinary artisan at the time the invention was made and therefore obvious in designing therapeutic regimens associated with inflammatory bowel disease.

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phillip Gambel/
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